REMARKS

Claims 1-5, 8-10, 16-17 are pending in the present application. By virtue of this response, new claim 18 has been added. Support for new claim 18 can be found in the specification at least at page 11, lines 3-15. Accordingly, claims 1-5, 8-10, and 16-18 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Information Disclosure Statement

The Examiner states that the Information Disclosure Statement (IDS) submitted 03/22/2006 has been considered by the Examiner. Applicant acknowledges that the Examiner has considered all references submitted on 3/22/06. The Examiner alleges that the publications retrieved from different internet sources and the international search reports are not true publications with a publication date, and therefore are not fully in compliance with 37 CFR 1.97 and thus they will not be printed on the face of the patent issuing from this application.

Applicants submit concurrently herewith a Supplemental Information disclosure Statement with two references discussed herein. Applicants respectfully request that the Examiner initial the Form PTO/SB/08a/b indicating her consideration.

Claim Rejections-35 USC § 112, First Paragraph

Claims 1-5, 8-10 and 16-17 remain rejected under 35 USC § 112, first paragraph as failing to comply with the enablement requirement.

Applicants traverse this rejection. The specification provides adequate guidance to enable claim 1-5, 8-10 and 16-17 in accordance with 35 U.S.C. §112, first paragraph.

The Examiner alleges at page 2 of the Office Action that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Examiner has not established a prima facie case for lack of enablement.

"To be enabling, the specification of a patent must teach those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation' . . . Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples." *See In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). With respect to the enablement requirement for patentability, the burden is on the Examiner to show that the specification is not enabling. MPEP § 2164.04 states that "[a] specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." The MPEP cites the decision in *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971), in which the court stated that the Patent Office, when making a rejection on the basis of nonenablement, must explain why it doubts the truth or accuracy of the disclosure by backing up its assertion with acceptable contrary evidence or reasoning.

The Examiner has failed to meet the burden of showing that the specification does not provide an enabling disclosure. Applicants respectfully submit that the specification provides all the information required for one of skill in the art to make and use the invention to suppress a RSV infection in an individual who has been exposed to RSV, as claimed.

The specification teaches how to make the claimed polynucleotides comprising an ISS. The specification teaches the requirements for the ISS. See page 17, lines 3-28; page 18, lines 1-8 and page 20, lines 8-24. The specification teaches how to synthesize ISS. See page 20, lines 25-28 and page 21, lines 1-28. The specification describes how to assay for a measurable immune response. See, for example, page 13, lines 9-16. The specification states that "ISS have been described in the art and *may be readily identified using standard assays* which indicate various aspects of the immune response, such as cytokine secretion, antibody production, NK cell activation

and T cell proliferation." Page 17, lines 3-10, emphasis added. The specification provides a number of references that describe ISS. See pages 3-4.

On page 17, lines 11-23, the specification teaches that "[t]he ISS can be of any length greater than 6 bases or base pairs and generally comprises the sequence 5'-cytosine, guanine-3', preferably greater than 15 bases or base pairs, more preferably greater than 20 bases or base pairs in length. The specification teaches that an ISS may also comprise the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, G-3'. The specification teaches that an ISS may also comprise the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine, C, C-3'. The specification teaches that an ISS may comprise (*i.e.*, contain one or more of) the sequence 5'-T, C, G-3'. The specification also teaches that in some embodiments, an ISS may comprise the sequence 5'-C, G, pyrimidine, pyrimidine, C, G-3' (such as 5'-CGTTCG-3'). The specification also teaches that in some embodiments, an ISS may comprise the sequence 5'-C, G, pyrimidine, pyrimidine, C, G, purine, purine-3'. The specification also teaches that in some embodiments, an ISS comprises the sequence 5'-purine, purine, C, G, pyrimidine, pyrimidine-3' (such as 5'-AACGTT-3'). The specification also teaches that in some embodiments, an ISS may comprise the sequence 5'-purine, T, C, G, pyrimidine, pyrimidine-3'. Furthermore, the specification teaches approximately 160 specific ISSs. See page 18, line 9 through page 20, lines 2.

The specification teaches that "[t]he ISS *can be synthesized using techniques and nucleic acid synthesis equipment which are well known in the art* including, but not limited to, enzymatic methods, chemical methods, and the degradation of larger oligonucleotide sequences. See, for example, Ausubel et al. (1987); and Sambrook et al. (1989)." Page 20, lines 25-28, emphasis added. Synthesis of an ISS would be routine in the art.

The specification teaches methods for assessing suppression of RSV infection. The specification teaches that "[r]hinitis, nasal mucous production, severity of cough, myalgia, elevated body temperature, and other symptoms of respiratory virus infection may be easily measured using simple tests and/or scales as are known in the art. Viral titer may be assessed in biological samples using standard methods known in the art." Page 35, lines 10-15.

The specification teaches sequence requirements for ISS, specific examples of ISS, and provides information regarding how to identify and evaluate other ISS using techniques that are well known in the art. Synthesis of ISS may also be achieved using techniques that are described in the specification and are standard in the art. Thus, the specification provides adequate guidance regarding how to make ISS.

The specification teaches how to use the claimed ISS. The specification provides guidance regarding administration of the claimed compositions. For example, see the specification at page 30. Suitable formulations and routes for administration are disclosed on page 31, lines 20 through page 33, line 17. In addition, the specification provides a working example. Although working examples are not required for enablement (MPEP §2164.02), the claimed invention is exemplified in Examples 1-5 provided on pages 38 to 44 of the specification. These examples demonstrate that in an art-accepted model of a respiratory virus, namely cotton rat infected with respiratory syncytial virus (RSV), ISS is effective at reducing viral titers especially if administered locally (*i.e.*, at a site of infection) and at a sufficient time before viral infection.

It would not require undue experimentation to make and use the claimed invention.

As discussed above, the specification provides guidance regarding *how to make* ISS as claimed. Such techniques are standard in the art. Moreover, sequence requirements for ISS are set forth in the specification, as well as approximately 160 examples of specific ISS polynucleotide sequences, and methods for identifying and testing additional ISS are described in the specification and are well known and available in the scientific literature. Methods for *how to use* ISS and for practicing the claimed methods are described in detail in the specification, in terms of formulations and routes of administration, as well as testing for modulation of an immune response, using standard techniques in the art. In addition, a working example is provided showing that in an art-accepted model of a respiratory virus, namely cotton rat infected with respiratory syncytial virus (RSV), ISS is effective at reducing viral titers especially if administered locally (*i.e.*, at a site of infection) and at a sufficient time before viral infection.

For a *prima facie* case of non-enablement, the burden is on the Office to demonstrate that there is a reasonable basis to question, the presumptively sufficient disclosure made by the

applicant. *See*, for example, *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993). Applicants respectfully submit that the Examiner has not produced adequate evidence to support a lack of enablement, *i.e.*, to establish that with the teachings provided in the specification, a person skilled in the art could not determine that RSV infection has been suppressed in an individual who has been exposed to RSV when a composition comprising a polynucleotide comprising an ISS comprising the sequence 5'-CG-3', wherein the polynucleotide is greater than 6 and less than about 200 nucleotides in length, is administered to the respiratory track of the individual, wherein the ISS is not administered in conjunction with an RSV antigen, an immunostimulatory cytokine, and an adjuvant.

"The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v.Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). Applicants submit that in the instant case, enablement is provided by the disclosure in the specification, and also by knowledge in the art about ISS polynucleotides. In addition to the guidance provided by the specification, immunostimulatory polynucleotides are well known in the art and polynucleotides with immunostimulatory sequences active in cells of many mammalian species have been described in the scientific literature, including humans, monkeys, chimpanzees, cows, swine, dogs, cats, rabbits, mice, and rats. In particular, much has been described about ISS activity in human cells and immunostimulatory sequences active in human cells have been the subject of much scientific and patent literature. It would not require undue experimentation to apply the foundation provided by the ISS art, in combination with the teachings of the specification, to identify ISS sequences that will be useful in the practice of the claimed invention.

The court found that the enablement requirement was satisfied by a "disclosure [that] provides considerable direction and guidance on how to practice [the] invention and presents working examples," in view of the fact that "[t]here was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known." *In re Wands*, 858 F.2d 731, 740 (Fed. Cir. 1988). As discussed above, the specification provides direction and guidance on how to practice the invention and presents working examples. Additionally, in view of the fact that much has been described about ISS activity in human cells and

immunostimulatory sequences active in human cells have been the subject of much scientific and patent literature, Applicants submit that there was a high level of skill in the art regarding ISS technology.

The court in *United States v. Telectronics.* held that "[s]ince one embodiment [was] . . . disclosed in the specification, along with the general manner in which its current range was ascertained, . . . other permutations of the invention could be practiced by those skilled in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 786 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). The Federal Circuit has stated that "[e]nablement is not precluded by the necessity for some experimentation such as routine screening." *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). Applicants respectfully submit that the specification provides a reasonable amount of guidance to the skilled artisan with respect to the direction in which the experimentation should proceed to optimize the teachings of the specification and the art and that any additional experimentation is well within the level of ordinary skill in the art, *i.e.*, no *undue* experimentation is required. Applicants respectfully submit that varying the nucleic acid sequence of oligonucleotides and testing the oligonucleotides for immunostimulatory activity by methods known in the art and disclosed in the specification, including the art accepted cotton rat model of infection, are well within the bounds of routine experimentation by one of skill in the art.

Therefore, given the guidance in the specification and in view of the working examples demonstrating that, in the art accepted animal model of a respiratory virus, namely cotton rat infected with respiratory syncytial virus (RSV), ISS is effective at reducing viral titers especially if administered locally (*i.e.*, at a site of infection) and at a sufficient time before viral infection, it would not require undue experimentation for a skilled artisan to practice the claimed invention. Applicants respectfully submit that the pending claims are in compliance with the enablement requirement and that the Examiner has not established a *prima facie* case for lack of enablement.

The Examiner at page 3 of the Office Action states that the full scope of the claimed invention is directed at suppressing RSV infection and not solely at the reduction in viral titer. The Examiner alleges that while the specification may demonstrate that the administration of an ISS without administration of an RSV antigen, an immunostimulatory cytokine and an adjuvant results

in the reduction of titer, the specification has not demonstrated the administration of an ISS to suppress viral infection. The specification defines "suppressing" viral infection to mean *any* aspect of viral infection, including amount or titer of virus. See page 11, lines 3-9. Thus, as taught in the specification, the amount or titer of virus is a measurement of virus infection and a method that reduces RSV titer is a method that suppresses RSV infection. As stated in the specification, RSV infection can be assessed by any means known in the art, including, but not limited to, measurement of RSV particles. See page 11, lines 10-13. The Examiner alleges that the specification has not demonstrated that the administration of an ISS suppresses viral infection. Section 112, first paragraph does not require that the specification provide any working examples, and compliance with Section 112, first paragraph does not require proof of clinical efficacy. However, the specification does provide working examples in an art accepted model of RSV infection, the cotton rat model. In the amendment filed March 20, 2006, Applicants submitted a reference entitled "The Cotton Rat in Biomedical Research" provided by the Animal Welfare Information Center Newsletter dated the Summer 1994, vol. 5, no. 2. This reference states at page 1 that the cotton rat has served as a model for an extensive list of human and rodent pathogens and "currently (that is, at the time of the publication), its use is most important in studies of human RSV". Applicants submit two additional references that support that the cotton rat is an accepted animal model for RSV. The reference entitled: "Oral Efficacy of a RSV Inhibitor in Rodent Models of Infection", Cianci et al., *Antimicrobial Agents and Chemotherapy*, July 2004, p. 2448-2454, states at page 2448 that studies of rodent models of RSV infection, chiefly using inbred BALB/c mouse and cotton rat, have contributed to the understanding of the pathogenesis and immunobiology of human RSV disease. At page 2449, it is stated that "[c]otton rat studies were used to demonstrate the efficacy of ribavirin and RSV immunoglobulin against RSV infection; these were prerequisite studies to the subsequent clinical trials leading to their licensure as therapeutic and prophylactic agents, respectively." At page 2453, it is stated that the cotton rat model of RSV infection can provide *in vivo* proof of principle for the antiviral efficacy of compounds. The reference entitled, "Experimental Models for Study of Common Respiratory Viruses, by W. Clyde, 1980, *Environmental Health Perspectives*, vol. 35, pp. 107-112, states at page 109 that "[a]lthough information on human lung pathology in RSV disease is not extensive, the cotton rat observations appear to supply a reasonable counterpart

in terms of the areas involved in the respiratory track." Cianci et al. and W. Clyde references are submitted on the Supplemental Information Disclosure Statement submitted concurrently herewith. In the instant specification, it is demonstrated that in the cotton rat model of RSV, namely cotton rat infected with respiratory syncytial virus (RSV), ISS is effective at reducing viral titers especially if administered locally (*i.e.*, at a site of infection) and at a sufficient time before viral infection. A reduction in viral titer correlates with suppression of virus infection.

The Examiner alleges at page 6 of the Office Action that while the claims recite the phrase "suppressing RSV infection", the act of inducing a specific immune response remains to be encompassed by the full scope of the invention. The Examiner further alleges that the specific immune response to be induced by the claimed invention is a Th1 type response and alleges that Th1 activity is dependent upon the presence of a disease specific antigen, as evidenced by Kobayashi. Applicants invite the Examiner's attention to the claimed invention which recites, "A method of suppressing a respiratory syncytial virus (RSV) infection in an individual who has been exposed to RSV, comprising administering a composition to the respiratory tract of said individual, said composition comprising a polynucleotide comprising an immunostimulatory sequence (ISS) to said individual, wherein the ISS comprises the sequence 5'-CG-3', wherein the polynucleotide is greater than 6 and less than about 200 nucleotides in length, wherein RSV antigen, an immunostimulatory cytokine, and an adjuvant are not administered in conjunction with administration of said composition, wherein the individual is a human and wherein said composition is administered in an amount sufficient to suppress an RSV infection." Claim 1 does not recite induction of a Th1 response, and the claim does not recite administration of a disease specific antigen. The Examiner alleges that "no where in the specification has Applicant demonstrated that the administration of an ISS in the absence of a disease specific antigen is capable of suppressing infection, reducing viral load to the extent that results in suppression of viral replication, reducing the time course of infection, reducing in the number of lesions and/or one or more symptoms, or eliminating the virus from an infected site or individual." Although no working example is required for compliance with Section 112, first paragraph, in the working example described herein, reduction in RSV titer, a measurement of suppression of RSV infection, is demonstrated with administration of ISS and *in the absence* of administration of a RSV antigen. The Examiner appears

to be dismissing data in the specification that demonstrates reduction of RSV titer upon administration of ISS *in the absence* of administration of RSV antigen. The Examiner must provide objective reasoning as to why she doubts the data disclosed in the specification. If the Examiner has evidence that supports that the data are not accurate, Applicant requests that the Examiner present that data on the record. Otherwise, the Examiner has provided no basis to dismiss or contradict data disclosed in the specification.

The Examiner alleges at page 6 of the Office Action that the quantity of experimentation is a burden that would be required of the skilled artisan practicing the invention, and concludes that this would lead to undue experimentation. As the court held in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), the test for enablement does not rest merely on the quantity of experimentation that would be required to practice an invention, "since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." Contrary to the Examiner's allegation that a quantity of experimentation would lead to undue experimentation, the court has held that a considerable amount of experimentation is permissible, if it is merely routine. The Examiner then refers to Fearon et al. as demonstrating that the extent of immune stimulation induced by an ISS depends upon many factors. The Examiner's reliance on Fearon et al. is misplaced, and the teachings of this reference do not render the claimed invention non-enabled. The Examiner states that the skilled artisan would have to "blindly experiment" with various aspects of the ISS. As stated above, sufficient guidance is provided in the specification as to how to make and use the claimed invention, and a considerable amount of experimentation is permissible, if it is merely routine. As discussed above, the specification teaches the requirements for an ISS; the specification teaches how to make and use the claimed polynucleotides comprising an ISS; the specification teaches how to assay for an immune response to the polynucleotides comprising an ISS; and numerous illustrative examples of ISS are disclosed in the specification. Provided with the teachings of the specification and the knowledge of ISS in the art, the skilled artisan would not have to blindly experiment as alleged by the Examiner. A considerable amount of

experimentation is permissible, if it is merely routine. Based on the teachings of the specification, one of skill in the art would be able to determine an ISS for human using routine experimentation.

Examples 1-2 demonstrate that an ISS that does not include a TCG element at the 5' end of the ISS reduced RSV titer in the animal model described when administered intranasally. The Examiner acknowledges that the ISS used by Applicant in Examples 1-2 is capable of reducing RSV titer in the animal model in the absence of a TCG motif at the 5' end. The Examiner alleges that Applicant has not demonstrated that the ISS used by Applicant is capable of providing stimulation across multiple species. The claims do not recite or require that an ISS provide stimulation across multiple species. Compliance with Section 112, first paragraph does not require that an ISS provide stimulation across multiple species. The Examiner alleges at page 8 of the Office Action that with respect to the presence of a TCG element "Applicant teaches one thing. The art teaches a different thing". The specification demonstrates that in the cotton rat model of RSV, namely cotton rat infected with respiratory syncytial virus (RSV), ISS, without a TCG element at the 5' end, is effective at reducing viral titers especially if administered locally (*i.e.*, at a site of infection) and at a sufficient time before viral infection. A reduction in viral titer correlates with suppression of virus infection and the cotton rat model is an art accepted model of RSV. The fact that a reference may suggest that a TCG motif at the 5' end of an ISS is necessary to induce an immune stimulation across multiple species in no way indicates that undue experimentation would be required to practice the presently claimed invention.

The Examiner at page 9 of the Office Action alleges that Applicant has not demonstrated that the activities observed in cotton rats with the administration of ISS would transfer to other mammals. As stated above, the cotton rat model is an art accepted model of human RSV. As disclosed in Cianci et al., supra, cotton rat studies were used to demonstrate the efficacy of certain drugs against RSV infection, and were used in prerequisite studies to subsequent clinical trials leading to the licensure of the drugs as therapeutic and prophylactic agents. Furthermore, compliance with Section 112, first paragraph enablement does not require proof of clinical efficacy. Additionally, Applicants submit that the possibility that the invention may not work in every species encompassed by a claim does not necessarily render the claim nonenabled, because a claim may

encompass inoperative embodiments. MPEP § 2164.08(b). In *Atlas Powder Co. v. DuPont*, 750 F.2d 1569, 1576 (Fed. Cir. 1984), the court stated that "[i]t is not a function of the claims to specifically exclude . . . possible inoperative substances." Further, the MPEP states that "[t]he standard [for enablement] is whether a skilled person could determine which embodiments. . . would be inoperative or operative *with the expenditure of no more effort than is normally required in the art*." MPEP 2164.08(b), emphasis added. In *Atlas Powder* forty percent of about 300 experiments performed by the appellee failed for one reason or another. However, the Federal Circuit upheld the lower court's finding that the experiments were designated as failures because they were not optimal under all conditions, and held that optimality is not required because one skilled in the art would know how to modify those failures to achieve a better result. As discussed above, a great deal of guidance is provided by both the specification and the knowledge in the art as to the claimed invention.

The Examiner at page 9 of the Office Action points to Silverman and alleges that there is variability in the ability of an ISS to stimulate an immune response. Even if there may be variability in the ability of an ISS to stimulate an immune response, this in itself does not render the claimed invention non-enabled. The fact that there may be different ISS that have different activities in different mammals does not render the claimed invention non-enabled. In *In re Wands*, the court held that the enablement requirement was satisfied even though only 4 of 9 antibodies analyzed (44%) were found to have the claimed binding requirements and those successful 4 were produced in only 2 of 10 fusion experiments. *In re Wands*, 858 F.2d 731, 783-39 (Fed. Cir. 1988).

An analysis of the factors set forth in In re Wands shows that the claimed invention is enabled.

As set forth in *In re Wands*, 858 F.2d 731,737 (Fed. Cir. 1988), several factors must be weighed in an enablement analysis. These factors include: (A) the breadth of the claims; (B) the nature of the invention; (C) the state of the prior art; (D) the level of one of ordinary skill; (E) the level of predictability in the art; (F) the amount of direction provided by the inventor; (G) the

existence of working examples; and (H) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The MPEP states that "[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others." The factors must all be considered in an enablement analysis; no one factor is dispositive. Applicants therefore provide the following enablement analysis using the factors set forth in *In re Wands*:

A. With respect to the breadth of the claims, the claims are directed to methods for suppressing RSV infection in an individual who has been exposed to RSV, comprising, in part, administering a composition comprising a polynucleotide comprising an ISS to said individual. ISS are well known in the art and may be identified and tested using techniques that are well-established in the art.

B. With regard to the nature of the invention, the invention relates to methods for suppressing RSV infection in an individual who has been exposed to RSV. Methods for assessing suppression of infection are disclosed in the specification and are well known in the art. Furthermore, a working example is provided which exemplifies the claimed methods.

C and D. As discussed above, the state of the prior art (factor C) and the level of one of ordinary skill (factor D) are high, because much has been written in both the scientific and patent literature about how to make and use ISS in several species.

E. With regard to the level of predictability in the art, it is predictable that many sequences within the parameters set forth in the specification are operable in the claimed invention, as demonstrated by the working example in the specification. The fact that the activity of a polynucleotide may be fine-tuned by sequence adjustments does not indicate unpredictability or a lack of enablement.

F and G. With respect to the amount of direction provided by the inventor (factor F) and the existence of working examples (factor G), Applicant disclosed a working example in the specification, showing that the methods of the invention work as claimed, and guidance is provided

in the specification regarding how to identify and assess additional ISS polynucleotide for use in the claimed methods.

H. With respect to the quantity of experimentation needed to make or use the invention based on the content of the disclosure, a number of examples of ISS polynucleotides are provided in the specification, including one which is exemplified in the claimed method in a working example, as well as disclosure teaching how to identify and evaluate other ISS. Further, numerous ISS are known in the art, as well as techniques to test them for immunostimulatory activity, for which references are provided in the specification and incorporated by reference (pages 3-4).

In conclusion and in view of the foregoing, the amount of experimentation needed to practice the claimed invention or make the claimed compositions is not undue. Applicants submit that the presently claimed invention is in compliance with Section 112 and request withdrawal of this rejection of claims.

Claim Rejections - 35 USC § 102(e)

Applicant acknowledges that the rejection of claims of 1-4, 8-20 under 35 USC § 102(e) has been withdrawn.

Claim Rejections - 35 USC § 103(a)

Applicant acknowledges that the rejection of claims 11-14 under 35 USC § 103(a) has been withdrawn.

Double Patenting

A. Claims 1-5, 8-10 and 16-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 11 of copending Application No. 10/898,512. When otherwise allowable subject matter has been determined, Applicants will address this provisional double patenting rejection.

B. Claims 1-5, 8-10 and 16-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/426,237.

When otherwise allowable subject matter has been determined, Applicants will address this provisional double patenting rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no.*. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 12, 2006

Respectfully submitted,

By _____

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